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To: FSIS Docket #97-013P

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Ken Saville

From: Ken Saville
Director of Quality Assurance & Sanitation
Preferred Meal Systems, Inc.

Re: Docket # **97-013P** – ***COMMENTS (Proposed RTE Regulation)***

I am concerned with the new proposed rules (Performance Standards for the Production of Processed Meat and Poultry Products). I feel that these regulations are pushing the industry and your agency further away from your goal of a "paradigm shift" from "command and control" regulation to performance standards. Although these regulations carry the title of "performance standards" they will result in an additional regulatory burden due to misinterpretation by your program employees tasked with enforcing these regulations. Over the last three years it has been clear that FSIS employees have not been properly trained in these regulations and are still using the "command and control" style of enforcement.

Since the implementation of HACCP in small plants I have had ongoing problems with the FSIS over the definitions of process categories. Your original Pathogen Reduction /HACCP final rule is flawed in that it defines process categories for us. It does not follow scientific HACCP principles. In developing a HACCP plan it is up to the processor to determine the process category, intended use and consumer of the finished product. Your regulations force us to classify our meals are RTE when in fact they are NRTE. My company produces frozen portion control entrees. Some contain fully cooked meat and/or poultry products, some contain no meat/poultry protein at all (vegetarian or pasta meals), and some contain meat/poultry in combination with other food components that have not been fully cooked. *ALL* of our finished meals require cooking by the end user. Common sense tells you that you can't eat these meals "as-is" because they are frozen. The *need* to be cooked before they are eaten. If we followed scientific HACCP principles (as opposed to regulatory HACCP) all of our meals would be classified as NRTE (not ready-to-eat). But, under the existing regulations, some of our meals must be classified as RTE because of the FSIS definition of RTE The clarification of process categories in FSIS Notice 23-99, Attachment 1 and FSIS Directive 10,240.1, Rev. 1, Amd. 1 has helped but we still have to deal with the inaccurate RTE classification. This causes us several problems. First, we are incurring an unnecessary burden of pathogen testing because of the hysteria generated by *Listeria monocytogenes*. *L. monocytogenes* is *NOT* an issue with our products because they are ALL supposed to be cooked before consumption. All of our packaging and labeling is clearly marked "Keep Frozen" and " Cook to a minimum of 160°F". (We support your proposed labeling regulation – 9 CFR §317.2 & §381.125) Second, we have to deal with panicked customers demanding that we test NRTE product for *L. monocytogenes*. We would appreciate it if the FSIS would communicate more facts and less sensationalism with regard to foodborne pathogens.

Before you issue any new regulations and performance stand: rds you should correct your Pathogen Reduction/HACCP rule by following the NACMCF H. ıCCP development guidelines and allow processors to make decisions about their products, pro esses, process categories, and food safety hazards without the burden of "one-size-fits-all" regul: tory determinations.

I wish to offer the following comments regarding the proposed r ıle for Performance Standards for RTE products.

Process Categories –

The Federal Register notice of February 27, 2001 lists "Entree: /dinners" as examples of RTE products.

Ref.: pp. 12591 – 12592 **Examples of RTE Products** (Table)

Cooked or Otherwise Processed Whole or Comminuted Pr(ducts

Meat

Entrees/Dinners
Pasta with Meat Sauce
Ravioli

Poultry (Includes Products Containing Any Amount of Poultry)

Entrees/Dinners

This characterization of these items as RTE is not entirely accur ıte. In my company products such as these are NRTE under both regulatory (FSIS Directive 1(), 240.1, Rev. 1, Amd. 1) and common sense guidelines. Please revise this chart. Please do N OT publish this in regulatory "guidance" documents. It will cause confusion among your ins)ectors. Some will say "you have to call it RTE because it says so in this book" – I've dealt wit ı this many times over the last 3 years, with multiple inspectors in multiple plants.

Process Categories – frozen entrees are not necessarily RTE be :ause they may contain other ingredients in a raw or semi-processed state . They should *NOT* b : listed as RTE products. The DRAFT of the proposed rule lists entrees and frozen meals as RTE This in not always the case.

Please CONTINUE the use of the table provided in FSIS Notice 2: -99 Attachment 1 and FSIS Directive 10,240.2 Rev. 1 Amend. 1 – *Microbial Testing Gui lelines for RTE Products.*

With regard to the meals my company produces the presence of *L monocytogenes* in our airline meals does not present a health hazard because they will be cooke ł on the plane before they are eaten.

The presence of *L. monocytogenes* in the natural microflora of raw and semi-processed vegetables, competitive exclusion by other native bacteria, the process category, and intended use of the meal (specifically the cooking step and holding time on the aircraft prior to consumption) are all factors that support this conclusion.

You are to be commended on the thorough explanation and foundation for the existing regulations contained in this notice of proposed rules. I agree with your scientific data for your determinations about lethality and stabilization. I wish to call to your attention the statement, "(*Listeria monocytogenes*) Although frequently present in raw foods of both plant and animal origin ..." found on page 12602 of the Federal Register notice.

This is precisely why I, and my company, am opposed to these new regulations. Following scientific (NACMCF) HACCP principles we have determined that our products are NRTE because (1) they contain raw and/or partially processed vegetables added to meat/poultry products and (2) our meals will be cooked by the end user before they are eaten. If your regulations force us to test for *Listeria monocytogenes* because you force us to classify our products as RTE then it is only a matter of tie before we have to recall product because of the presence of this pathogen. How can our meals be "adulterated" when *Listeria monocytogenes* is part of the natural microflora of the vegetable we add to our meals.

We support pathogen testing for RTE products. *Listeria monocytogenes* is a significant food safety hazard for a product that is to be consumed as is, right out of the package. But this does not apply to our product line. We do not want to be forced into a no-win situation because of flawed regulatory language.

We do not feel that these new regulations are necessary. If you choose to issue them anyway we would hope that you carefully rewrite the definitions for RTE and NRTE products. We would prefer that you remove the pre-defined process categories in 9 CFR part 417 and let the establishment make the decision. I've got plenty of scientific data to support my position. We add raw vegetable to our meals. Many authors (including the FSIS, in this docket) have cited that *Listeria monocytogenes* is "frequently present in raw foods of both plant and animal origin".

We are also concerned about your assertions that *Listeria monocytogenes* must be addressed in the HACCP plan. If its present in raw foods and our products are NRTE is it a risk? No. Please put that in writing. I can't even begin to count the number of times I've had to justify and document this for FSIS program employees and our customers. If your agency would present ALL the facts and define which products are NOT at risk as well as those that are that would simplify everyone's life.

We believe that you are headed in the right direction, specifically with your decision to reclassify hot dogs and frankfurters as NRTE. That's the kind of objective, common sense approach we're looking for.

We are opposed to the mandatory *Listeria* testing proposed in 9 CFR §430.4 – we feel that the current voluntary system is more than adequate. With the existing flaws in the current Pathogen Reduction/ HACCP regulation [9 CFR §417.2(b)] this will add to the confusion surrounding Listeria monocytogenes as well as fuel the public's hysteria about his pathogen. Unnecessary testing and product recalls have the potential of enormous financial loss to establishments that could lead to an establishment going out of business. Excessive recalls also have the detrimental effect of desensitizing the public to the risk of foodborne illness.

Most people, including your front-line inspection personnel, do not have the academic training and practical experience in microbiological to make informed decisions about microbial risks.

Please consider these comments carefully in making your decision about implementing the regulations proposed in the Federal Register of February 27, 2001. We feel that the most appropriate course of action is "No Action" – the alternative you cited on page 12633 of the Federal Register notice.

Ken Saville, *Director of Quality Assurance & Sanitation*
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